IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	)	
	:	
Junichi Shimada, et al.	)	
	:	Group Art Unit: 1614
Serial No. 10/692,930	)	
	:	Examiner: Phyllis, Spivack G
Filed: October 27, 2003	)	
	:	
For: Therapeutic Agent for Neurodegenerative Disorders)	)	

DECLARATION

The Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Sir:

I, Shunji Ichikawa of 825, Kannami-cho Hita, Tagata-gun, Shizuoka, 419-0125, Japan, do declare as follows:

I joined Kyowa Hakko Kogyo Co., Ltd in April, 1969. During 1971-1973, I was engaged in the research on the efficacy and general pharmacology of L-DOPA as an antiparkinson drug in rodents. During 1974-1977, I was engaged in the examination of the anxiolytic and general pharmacological effects of flurazepam in rodents. I was involved in the general pharmacological tests for micronomicin sulfate, an aminoglycoside antibiotic, and levamisole hydrochloride in

rodents during 1983-1986 and 1987-1990. From 1990, I was engaged in the evaluation of the facilitatory effects of domperidone etc. on gastrointestinal motility in animals. Since 2000, I have been in charge of efficacy pharmacology and safety pharmacology in the exploratory pharmacology department at Pharmaceutical Research Institute of the company.

The following experiment was conducted under my direction.

EXPERIMENT

The protective effects of Compound 1 of the present application against cerebral ischemia in Mongolian gerbils were examined.

Method:

Male Mongolian gerbils, 10 weeks old, were used. Ten animals were assigned to each group. Reserpine (5 mg/kg) was injected intraperitoneally to the gerbils. One day later, the right carotid artery of each gerbil was completely occluded under anesthesia. At 30 minutes after the occlusion, the animals were given vehicle (0.5 % methyl cellulose), 0.1 mg/kg of Compound 1 orally and then monitored with respect to the mortality for 12 hours after the occlusion. The result is shown in Table 1.

Result:

Table 1. The protective effects against cerebral ischemia in Mongolian gerbils

Drugs (0.1 mg/kg, p.o.)	Survival animals / Total animals (at 12 hours after occlusion)
Vehicle	0 /10
Compound 1	10 /10

Conclusion:

All animals died in the vehicle group within 12 hours after the occlusion. However, Compound 1 prevented the mortality.

The undersigned declarant declares further that all statements made herein of his knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Executed this 13th day of January , 2006.

Shunji Ichikawa

Shunji ICHIKAWA